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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,042	11/16/2001	Hiroyuki Miyata	0283-0161P	7946

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,042

Applicant(s)

MIYATA ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-10, 14 and 15 are currently pending in the instant application. Claims 1-10 and newly added claim 15 are rejected. Claim 14 has utility and also appears allowable over the prior art of record. Claims 1-5 and 7-8 were amended, claims 11-13 were cancelled and claim 15 was added in the amendment filed 15 April 2003.

Response to Arguments

Applicant's arguments to the 35 USC 101 and 112 1st paragraph rejections filed 15 April 2003 have been fully considered but they are not persuasive. On page 12 of applicant's amendment filed 15 April 2003, applicant's representative argues that Exhibit A (Cossy et al.) shows that the 5-(n-propyl)proline methylester, produced in the additional reference example in the declaration filed 30 October 2002, has a specific and substantial utility. Applicant's representative states that Exhibit A shows that 1-benzoyl-5-(n-propyl) proline methyl ester serves as a synthetic intermediate for producing (-)-pseudoconhydrine which has biological properties. Applicant's representative further states that treating 5-(n-propyl)proline methyl ester with benzoyl chloride in the presence of a base would produce 1-benzoyl-5-(n-propyl) proline methyl ester and shows a reaction on page 13 which discloses applicants claimed compound preparing a 5-substituted proline ester. These arguments and Exhibit A are insufficient to overcome the rejections of claims based upon 35 USC 101 and 112 1st paragraph as set forth in the last Office action because: Applicant has not shown by evidence how all the species encompassed by the compound of formula (I) as found in claim 1 have utility. While applicant has previously shown that the compound of claim 14 has utility

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by the example 1 in the declaration which discloses how to prepare 5-methylproline methyl ester, which has a specific utility as found in EP 0 618 926, from the compound of claim 14, again, as mentioned in the previous office action, this cannot be concluded to provide evidence for all compounds of the formula (I) as found in claim 1. The additional reference example in the declaration filed 30 October 2002 and now the Exhibit A, filed 15 April 2003 still do not provide evidence that any of the claimed compounds of the formula (I) as found in claim 1 have utility since neither the additional reference example, nor Exhibit A provide evidence that 5-(n-propyl)-proline methyl ester has any utility and therefore, has not provided an example of utility for 3-(R)-1-phenylethyl-7a-methoxy-6-propyl-4H-pyranol [3,2-d]-oxazol-2(3H)-one. While Exhibit A shows that 1-benzoyl-5-(n-propyl) proline methyl ester has a utility, it does not show that 5-(n-propyl)-proline methyl ester has a utility. While applicant's representative has argued that the 1-benzoyl-5-(n-propyl) proline methyl ester could be produced from the 5-(n-propyl)-proline methyl ester and provided a reaction showing applicants claimed invention preparing a 5-substituted proline ester, these arguments cannot replace what is lacking in the instant specification and Exhibit A for the utility of the compounds of the formula (I) as found in claim 1, which is that neither the specification nor exhibit A show a utility for the 5-(n-propyl)-proline methyl ester. Neither the specification nor Exhibit A show how to produce 1-benzoyl-5-(n-propyl) proline methyl ester from the 5-(n-propyl)-proline methyl ester. Therefore, since the Exhibit A has not provided a utility for the 5-(n-propyl)-proline methyl ester, the specification and Exhibit A fail to provide how to prepare 1-benzoyl-5-(n-propyl) proline methyl ester from 5-(n-propyl)-proline methyl

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ester and applicants arguments cannot replace what is lacking in the specification and Exhibit A, the rejections under 35 USC 101 and 112 1st paragraph are maintained

Maintained Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 and newly added claim 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

For essentially the same reasons as those set forth in Papers No. 2 and 10, claims 1-4, 7-10 and 15 lack a specific or substantial asserted utility or a well established utility because the specification provides the utility for the claimed compound of formula (I), as found in claim 1, as a "starting material or an intermediate for synthesizing a pharmaceutical product or an agricultural chemical and as a starting material for synthesizing other fine chemical products (page 1, lines 10-15). This utility is not a substantial utility that defines a "real world" use. According to the MPEP section 2107.07 "substantial utility" is defined as a utility that does not require further research to identify or confirm the "real world" context of use. An example, according to section 2107.07 of the MPEP, of a utility that requires carrying out further research to identify or confirm the context of use is "a claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility." There are many pharmaceutical products that are useful for treating many different diseases, however, there is no known pharmaceutical product that is useful in treating all

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diseases. Without specific examples of pharmaceutical products and direction towards treatment of types of diseases, it would require someone of ordinary skill in the art further research to identify the use of the claimed compound. In the instant case, the only example compounds produced by applicants claimed compounds is 5-methylproline methyl ester (from page 41 of the specification and page 3 of the declaration) and 5-(n-propyl)-proline methyl ester (page 5 of the declaration). The 5-methylproline methyl ester has a specific utility as found in EP 0 618 926, while the 5-(n-propyl)-proline methyl ester has no stated specific or substantial utility. The showing of utility for the intermediate 5-methylproline methyl ester only provides utility for the specific compound of claim 14. The production of 5-(n-propyl)-proline methyl ester does not provide support for a specific and substantial utility since no utility is given in Exhibit A, the specification or the declaration for this intermediate and the pharmaceutical products and agricultural compounds are still not given in examples and a direction for use of the final products is not given. Besides the example of 5-methylproline methyl ester as one of the products of the claimed compound in a reaction, the applicant fails to provide direction so that one of ordinary skill in the art would know how to use any other claimed compounds but that of claim 14. Again, EP 0618926 and the declaration under 35 U.S.C. 1.132, which has established utility for the specific compound of claim 14, has not established utility for all the compounds of formula I as instantly claimed and Exhibit A has not provided any evidence of utility for the additional reference example of 5-(n-propyl)-proline methyl ester, i.e. these other compounds of formula I have not been shown to be useful for the preparation of the known intermediate, 5 methylproline

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methyl ester which has a utility which is disclosed in EP 0 618 926. The declaration under 35 U.S.C. 1.132 fails to show how any other claimed compounds of the formula I can be used to make the known intermediate of 5 methylproline methyl ester. The second example of the declaration shows how to make 5-(n-propyl)-proline methyl ester, which is not shown to have a substantial utility and is not found as a starting material in EP 0618926 or Exhibit A.

In regards to the production of agricultural chemicals as the use for the claimed compound, agricultural chemicals can be used in various ways such as pesticides, fungicides, and herbicides. Without specific examples of agricultural chemicals or a direction towards the general use of these agricultural chemicals, it would require someone of ordinary skill in the art further research to identify the use of the claimed compound. Finally, the use of the claimed compound as starting material or an intermediate to make fine chemical products without specific examples of these fine products or their intended use requires someone of ordinary skill in the art to perform further research to identify the use of the claimed compound. Therefore, claims 1-4, 7-10 and 15 are rejected because the specification fails to provide a specific and substantial utility for the compounds as claimed.

In view of the lack of utility rejection of claims 1-4, 7-10 and claim 15, claims 5-6 are also rejected. According to MPEP 2107.07, another example of a utility that requires further research to identify or confirm the context of use is "a method of making a material that itself has no specific, substantial, and credible utility. Since the claimed

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compound has no substantial and specific utility, the process of making the compound as claimed in claims 5-6 is also rejected under lack of utility.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and newly added claim 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Maintained Allowable Subject Matter

Claim 14 appears allowable over the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

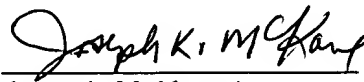
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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